

**Notice of Allowability**

Application No.

10/520,330

Applicant(s)

HAMADA ET AL.

Examiner

Paul C. Martin

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 06/18/07.
2. ☒ The allowed claim(s) is/are 1, 3 and 4.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                     |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|  | 9. <input type="checkbox"/> Other _____   |

**DRAFT**

**EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Douglas Mueller on 08/31/07.

The application has been amended as follows:

**IN THE CLAIMS:**

Cancel Claims 9-11.

1. A method for testing peritoneal function in order to evaluate the a condition of a peritoneal dialysis patient, comprising the steps of:  
alternately and repeatedly infusing and draining performing fluid infusion and fluid drain  
of a predetermined amount of peritoneal dialysis fluid with in alternation for a first  
peritoneal dialysis fluids having a first ~~higher~~ osmotic pressure and a second ~~lower~~  
peritoneal dialysis fluid having an osmotic pressure lower than the first osmotic  
pressure;

analyzing the drain fluid in order to assess both the ~~an~~ amount of the peritoneal dialysis fluid that is retained within the abdominal cavity of a patient, and the a concentration of monitored solutes in the peritoneal dialysis fluid for each time of the fluid drain;

performing a peritoneal equilibrium test ~~with respect to the peritoneal dialysis patient,~~ by infusing a dialysis fluid, repeating for predetermined times and at predetermined time intervals draining ~~of~~ the dialysis fluid, sampling some of the drained fluid, returning the drained fluid to the patient, and then draining the dialysis fluid; and

performing a blood test in order to assess concentrations of the monitored solutes; wherein the fluid infusion and the fluid drain is performed at least three times for each of the dialysis fluids of the respective osmotic pressures, a dwell time from when the dialysis fluid is infused until when the dialysis fluid is drained being set to be different each time when using dialysis fluid having the same osmotic pressure,

the repetition of the fluid infusion and the fluid drain is performed in the order such that the dialysis fluid of the higher osmotic pressure is used for the first and the last times, ~~and the dialysis fluid used for each of the other times is determined so that the dialysis fluid of the higher osmotic pressure is not continuously used,~~

the step of performing the blood test is executed only once; and

the peritoneal equilibrium test is performed last of all the steps, and the blood test is performed immediately before the peritoneal equilibrium test, or is performed during the peritoneal equilibrium test.

Claims 1, 3 and 4 are allowed.

The following is an examiner's statement of reasons for allowance: The closest prior art of record, Chen *et al.* (US 5,670,057) and Milner *et al.* (US 6,077,836) do not teach or suggest the method step of repeatedly infusing and draining two peritoneal dialysis fluids wherein one dialysis fluid has a lower osmotic pressure than the other, in repeated alternation.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

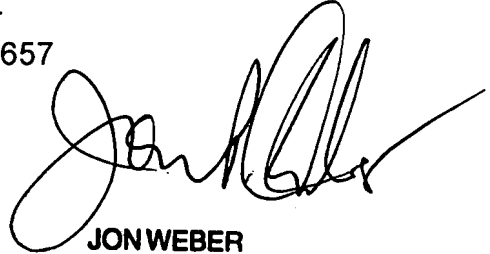
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin  
Examiner  
Art Unit 1657

09/04/07



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**